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PRE-APPEAL BRIEF REQUEST FOR REVIEW		06530.0311		
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on	First Named Inventor			
Signature	Otto E. ANDERHUB			
Typed or printed name	Art Unit	Art Unit Examiner		
Halle	3734		Lindsey M. BACHMAN	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.				
I am the				
applicant/inventor.	Parmita Chattyce Signature			
assignee of record of the entire interest.				
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.			romita Chatterjee ped or printed name	
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attorney or agent acting under 37 CFR 1.34.				
Registration number if acting under 37 CFR 1.34		S	eptember 29, 2010 Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.				

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re Application of:	(
Otto E. ANDERHUB et al.) Group Art Unit: 3734
Application No.: 10/720,668	Examiner: BACHMAN, Lindsey M.
Filed: November 25, 2003))
For: A FORCEPS AND COLLECTION ASSEMBLY AND RELATED METHODS OF USE AND MANUFACTURE) Confirmation No.: 6222))

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of the rejections set forth in the final Office Action mailed March 29, 2010 ("the final Office Action"). Claims 1, 2, 6-27, 31-50, 52-65, and 87-106 are pending in this application, with claims 91-94 having been withdrawn from consideration. Claims 1, 11, 26, 35, and 50 are independent. In the final Office Action, the Office maintained a restriction by original presentation and withdrew claims 91-94 from consideration; and rejected the pending claims under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,440,085 to Krzyzanowski ("Krzyzanowski") in view of one or more of International Publication No. WO 02/39810 A2 to Caisley ("Caisley") and U.S. Patent No. 5,482,054 to Slater ("Slater"). For at least the following reasons, Applicant requests withdrawal of the outstanding rejections.

Rejections under 35 U.S.C. § 103(a) based on Krzyzanowski and Caisley

Independent claims 11 and 35 recite, among other aspects, a cutting portion and a holder,
"wherein the cutting portion and the holder are comprised of metal." In stark contrast to independent
claims 11 and 35. Krzyzanowski is directed to a method of assembling a non-metallic biopsy forceps

jaw device. For example as explained on pages 26 and 27 of the Amendment filed on January 8, 2010, the entire disclosure, including abstract and claims, is directed to non-metallic biopsy forceps jaw assembly.

Page 4 of the final Office Action acknowledges that Krzyzanowski "teaches the advantage to using plastics, rather than metals in surgical tools" and then summarily dismisses the express teaching of Krzyzanowski by concluding that the "construct[ion] [of] a known object out of metal does not constitute a patentable difference over the prior art." Applicant submits that this is an improper analysis under Section 103. As stated in the M.P.E.P., "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. § 2141.02(VI) (internal citations omitted) (emphasis added). An obviousness rejection cannot selectively utilize teachings or features from a reference to support the rejection, while entirely disregarding teachings or features that would make the rejection inappropriate.

As noted on pages 26 and 27 of Applicant's January 8, 2010, Amendment, the entire disclosure of Krzyzanowski expressly teaches away from having a cutting portion and a holder comprised from metal. Indeed, the background of the invention, relied on by the final Office Action in support of the rejection of the claims, explains the alleged disadvantages of having metallic biopsy jaws. For example, according to Krzyzanowski, methods of making devices with metallic components "require[] meticulous effort to align and secure the metallic components of the jaw. This results in costly and time consuming assembly." See col. 1, II. 24-26 of Krzyzanowski. Therefore, Krzyzanowski teaches that "[a]n object of one aspect of the present invention is to provide an improved method of assembly of a non-metallic biopsy forceps jaw." See col. 1, II. 61-64 of Krzyzanowski also teaches the alleged "[a]dvantage of [its] invention [to] include the use of non-metallic materials for the biopsy jaws thereby allowing the snap-connections of the upper and lower jaws and the activating wires with the

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jaws ... Furthermore, the use of non-metallic components makes the device cheaper and therefore disposable if desired." See col. 2, ll. 44-55 of Krzyzanowski.

Since <u>Krzyzanowski</u> explicitly teaches its intended purpose is to have biopsy jaws comprised of non-metallic materials, the Office's proposed modification would be contrary to the explicit teaching of <u>Krzyzanowski</u>. It is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D). Accordingly, it is requested that the rejection of independent claims 1 and 35 be withdrawn and the claims allowed.

Furthermore, each of independent claims 1, 11, 26, and 35 recite, among other aspects, "a jaw assembly having a cutting portion for mating with the first jaw to cut a tissue sample, a holder; and a storage portion configured to store tissue samples."

Page 4 of the final Office Action asserts that lower jaw 26 of Krzyzanowski corresponds to the claimed holder and cutting edge 27 corresponds to the claimed cutting portion. Applicant respectfully disagrees. While page 5 final Office Action concedes that Krzyzanowski fails to disclose "a removable storage portion," the final Office Action alleges that Caisley discloses this feature. The final Office Action contends that "[i]t would have been obvious to one of ordinary skill in the art to modify the device of krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient." See page 5 of the final Office Action. Applicant respectfully disagrees.

Even if the device of <u>Krzyzanowski</u> were modified to include the alleged storage portion of <u>Caisley</u>, as proposed by the final Office Action, the storage portion of the modified <u>Krzyzanowski</u> device would not be "configured to receive tissue samples," as required by claim 1. Specifically, <u>Krzyzanowski</u> teaches that a non-metallic jaw assembly 22 including an upper jaw 30 and a lower jaw 26 having a cutting edge 27 insert molded and/or snap connected thereto is mounted about a single flat support 14. See Fig. 1, and col. 3, ll. 38-58 of <u>Krzyzanowski</u>. As illustrated in Fig. 9, when upper jaw 30 and lower jaw 26 are in an open configuration a pointed distal end 20 of single

flat support 14 is exposed. Pointed distal end 20 of flat support 14 is provided to skewer and secure a tissue sample captured between upper jaw 30 and lower jaw 26 while cutting edge 27 separates the tissue sample from e.g., an organ wall. Therefore, in contrast to independent claim 1, a tissue sample obtained with the Krzyzanowski device would be skewered to and retained by the distal end of the single flat support 14 after the tissue sample has been separated from the organ wall. The tissue sample would therefore be prevented from "falling" into any storage container secured to the Krzyzanowski device. Consequently, the tissue sample would not be received in such a storage container. Thus, such a storage container would not be configured to receive a tissue sample. Additionally, Applicant submits that for at least these same reasons, one of ordinary skill in the art would have no motivation to modify the device of Krzyzanowski to include a storage container such as the sample container taught by Caisley. Accordingly, it is requested that the rejection of independent claims 1, 11, 26, and 35 be withdrawn and the claims allowed.

Rejections under 35 U.S.C. § 103(a) based on Krzyzanowski, Caisley, and Slater

Independent claim 50 recites an endoscopic instrument comprising, among other aspects, a second end effector having "a non-straight portion connecting a tang to a cutting edge and configured to be received in a correspondingly-shaped gap in [a] holder."

In formulating the rejection of claim 50, the Office acknowledges that Krzyzanowski and <a href="Caisley" do not teach a non-straight portion connecting a tang to a cutting edge." See page 7 of the final Office Action. Page 8 of the final Office Action, however, cites conductive skeleton portion 418 shown in Figs. 8a-8c of Slater and contends that "Slater'054 shows that it is known to connect a cutter (418; Fib 8b) with a non-straight portion (portion 418 between bore 30 and cutting element 20 in Figure 8b) to a tang." Page 8 of the final Office Action then asserts "[t]he claim would have been obvious because the known technique using a tang and non-straight connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art."

Applicant respectfully disagrees.

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Krzyzanowski teaches away from using a metallic skeleton, such as the conductive skeleton portion 418 taught by Slater. In the section titled "Background of the Invention," Krzyzanowski discusses methods of manufacturing end effectors "by insert molding a non-metallic or ceramic or other non-conductive body around a metallic or otherwise conductive core," including those utilizing a metallic skeleton. See col. 1, Il. 29-48 of Krzyzanowski. Krzyzanowski then expressly rejects these methods of assembly, stating that they are not applicable for non-metallic biopsy forceps jaw devices and do not allow for "easy assembly and the use of less costly parts." See col. 1, lines 54-57 of Krzyzanowski. Accordingly, Krzyzanowski explicitly teaches away from modifying the cutting edge 27 to include the non-straight portion connecting a tang to a cutting edge as described in Slater. It is improper to combine references where the references teach away from their combination.

M.P.E.P. § 2145(X)(D). Accordingly, for at least this reason, it is requested that the rejection of independent claim 50 be withdrawn and the claims allowed.

Dependent claims 2, 6-10, 12-25, 27, 31-34, 36-49, 52-90, and 95-106 depend either directly or indirectly from independent claims 1, 26, and 50 and are allowable for at least their dependence on independent claims 1, 26, and 50.

Since the rejections include factual and legal deficiencies with regard to 35 U.S.C. § 103(a) and the M.P.E.P., Applicant is entitled to a pre-appeal brief review. Based on this Brief and the January 8, 2010, Amendment, Applicant requests that the rejections be withdrawn and the claims allowed. Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 29, 2010

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